



# ***Got Funding?***

## ***Tips for Efficiently Managing Your SBIR/STTR Award***

**November 9, 2021**

***Moderator - Rob Vinson***

**Small Business Program Manager**

**SEED (Small business Education & Entrepreneurial Development) | Office of the Director | Office of Extramural Research**



- Format and Introductions
- Tips for Efficiently Managing Your Award:
  - \* Program Officer
  - \* Grants Management Specialist
  - \* Operations Officer
- Questions & Answers

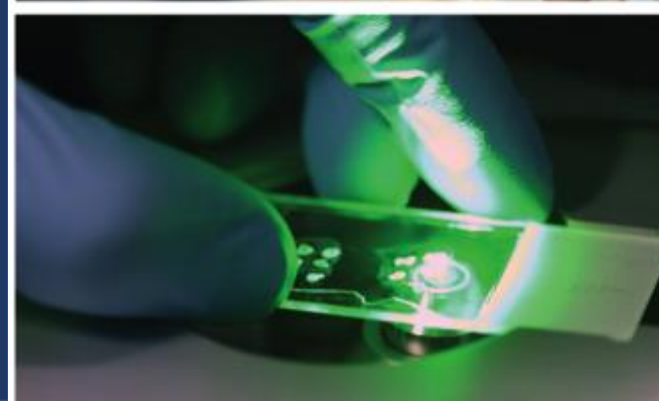
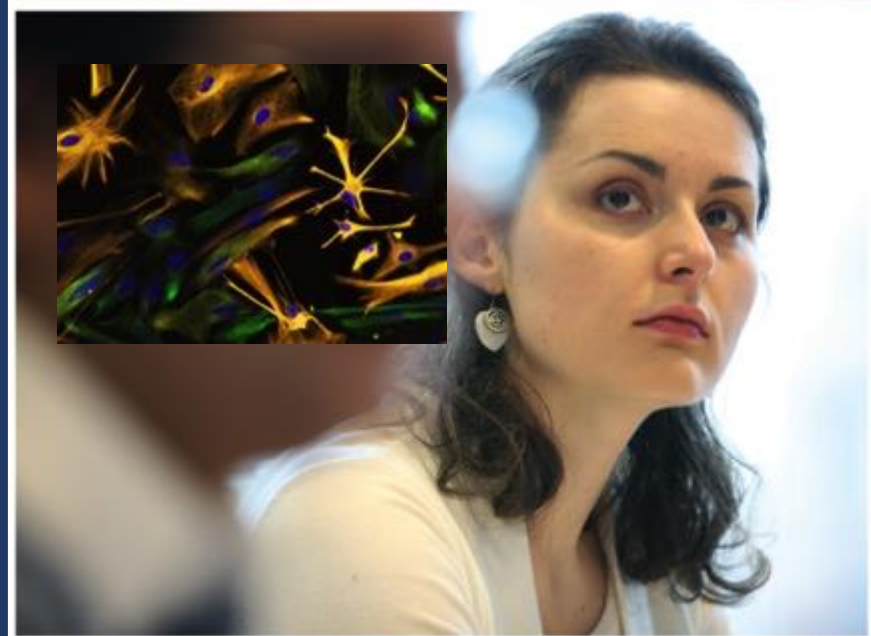
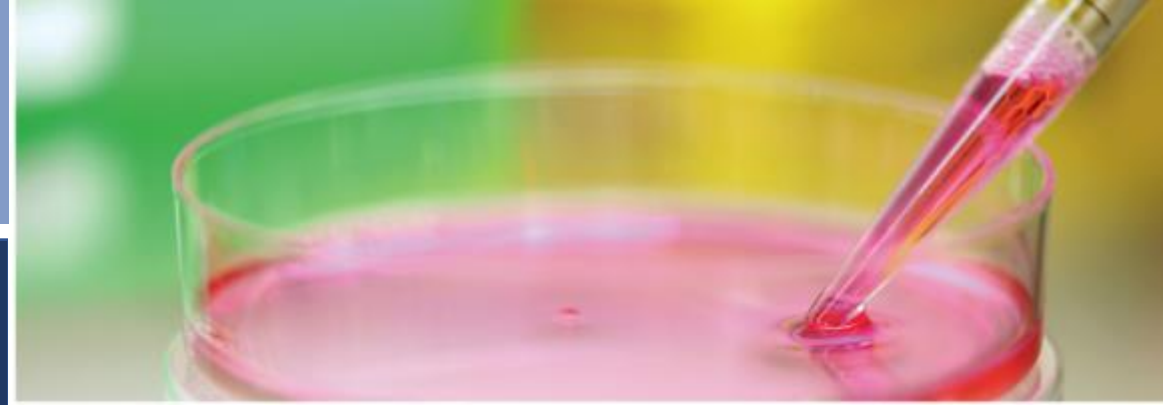


# Got Funding?

## Program Tips for Efficiently Managing Your SBIR/STTR Award

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# Read your Notice of Award

## Understand the Terms & Conditions of your award

- Some NoAs may have requirements for data sharing and/or meeting attendance
- Clinical Trial awards may have special Terms and Conditions

## Note any RESTRICTIONS

- Your award may be issued with a restriction on some or all research activities and funding. **If your NoA includes a restriction, you MUST meet the criteria to remove the restriction before proceeding with prohibited spending and activities.** Common Restrictions include:
  - Animal research, pending OLAW approval
  - Human Subjects Research, pending IRB approval

**DO NOT SPEND RESTRICTED FUNDS OR CONDUCT RESTRICTED ACTIVITIES UNTIL RESTRICTIONS ARE REMOVED IN A REVISED NoA**

## Review your approved budget

- Does your budget align with your application? Do you need to re-allocate funds more than 25% per category?

## Note Key Personnel listed in the NoA

- Key Personnel may differ from those listed in your application



# Know when to loop in your Program Officer (PO)

When you receive your award, you are approved to proceed with the research plan as described in your application. **If you want to change your R&D plan, team, or partners, please contact your PO *in advance* to determine whether NIH approval is necessary.**

**Scope changes, changes to Key Personnel, rebudgeting, change of institution, and foreign components\* are just some of the actions that require prior approval from your Program Officer and NIH.**

## **Common changes that should be discussed with your PO:**

- Change in animal research plan, including change in animal model
- Change in human subjects research plan
- Change in research partners – especially if key personnel named at partner sites
- Changes to company ownership that may impact SBIR/STTR eligibility
- Change in key personnel effort
- Inclusion of any foreign component\*

More information available at:

- [https://grants.nih.gov/grants/policy/nihgps/html5/section\\_8/8.1.2\\_prior\\_approval\\_requirements.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.1.2_prior_approval_requirements.htm)
- <https://sbir.nih.gov/about/eligibility-criteria>

*\* Note that SBIR/STTR policy generally prohibits use of SBIR/STTR funding for foreign work*



## Entrepreneurial Development Programs for NIH-funded small businesses:

### I-Corps

A six-week entrepreneurial immersion course that uses a hypothesis-driven method of customer discovery in order to gain insights into the issues associated with technology commercialization.

<https://sbir.cancer.gov/programseducation/icorps>

### C3i

The Concept to Clinic: Commercializing Innovation (C3i) Program is an annual course series designed to provide medical device innovators with the specialized business frameworks and essential tools for successful translation of biomedical technologies from the lab to the market.

<https://www.nibib.nih.gov/research-program/c3i-program>

# NIH resources offered to SBIR/STTR award recipients

## Supplement Opportunities:

- **TABA Supplement** – Supports up to \$6,500 in Phase I and \$50,000 in Phase II for TABA services  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-062.html>
- **Diversity Supplement** – Supports diverse research staff hiring and training for R&D related to your funded project  
<https://grants.nih.gov/grants/guide/pa-files/PA-21-345.html>
- Ask your PO what additional supplement opportunities your awarding IC may participate in

## SEED Innovator Support

- Free Consulting on Regulatory, Reimbursement, IP, and Company Development topics
- NIH-sponsored Showcase Opportunities at partnering conferences (BIO, RESI, Medtech, etc)  
<https://sbir.nih.gov/resources/entrepreneurs-in-residence>



# Got Funding? Tips for Efficiently Managing Your SBIR/STTR Award

Artisha Wright

November 9, 2021

*Other Transaction Authority Lead Agreement Specialist*

*OGM Other Transactions Authority and Compliance Branch*

# Read your Notice of Award!

## 1. What is the Notice of Award (NoA)?

- Legal Document issued to notify the organization that an award has been made.
- Issued for the initial budget period

## 2. What does the Notice of Award Contain?

- Budget/Project Period Dates
- Funding Commitment
- Terms and Conditions
- Grants Management Specialist and Program Official Contact Information

## 3. How does award acceptance occur?

- Draw down or request of funds from the Payment Management System

**\*Contact your Grants Management Specialist with any questions or concerns regarding the information in the NoA!**



# Post Award Communication with Grants Management

1. Issues with Payment Management System setup/access
2. Prior Approvals
3. Eligibility



# NCATS

**COLLABORATE. INNOVATE. ACCELERATE.**

 [ncats.nih.gov](https://ncats.nih.gov)

 [@ncats\\_nih\\_gov](https://twitter.com/ncats_nih_gov)

 [@ncats.nih.gov](https://facebook.com/ncats.nih.gov)

 [NIH-NCATS](https://linkedin.com/company/NIH-NCATS)



**NIH** National Center  
for Advancing  
Translational Sciences

# Got Funding?

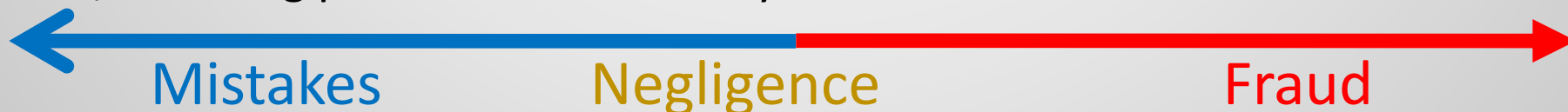
## Tips for Efficiently Managing Your SBIR/STTR Award

**Presented by:**  
**Jonelle Soeffing**  
**OIG, HHS**



# HHS-OIG Mission

- Ol's mission is to protect the integrity of HHS programs. Ol conducts Criminal, Civil, Administrative investigations of fraud, waste, abuse and misconduct.
- Fraud, waste and abuse typically fall into one or more of three general categories:
  - Conflicts of Interest
  - Theft of government funds/Embezzlement
  - Failing to Properly Support the Use of Funds
- Fraud: intentionally submitting false information to the Government or a Government contractor to get money or a benefit.
- Waste: practices that, directly or indirectly, result in unnecessary costs, such as overusing services and misusing resources.
- Abuse: Intentional or unintentional, thoughtless or careless expenditure, consumption, mismanagement of government resources; Excessive or improper use of government resources, including position and authority.



# Fraud Schemes

- False information on grant applications, progress reports, etc.
- Creating fictitious records: fabricated companies and invoices
- Using funds for unauthorized purposes
- Not doing any work
- Kickbacks
- PI outside employment
- Awardee company size misrepresentation
- **Specific examples of what NOT to do:**
  - Operate out of your residence (without authority)
  - Use grant funds for personal expenses
  - Pay others to do ALL of the proposed research
  - NOT pay institutions who did do the proposed work but still draw down the grant funds
  - Lie to the awarding entity – including on your biosketch

# Fraud Awareness

- Without understanding what fraud, waste, or abuse “looks” like, you may inadvertently commit it and be on the radar.
- Fraudsters utilize SBIR funds that may otherwise be given to legitimate awardees, so in essence they are stealing from everyone listening.
- Use the grant money for what you said it would be used for - no more, no less - and there won't be a problem.
- If you see something, say something

# Fraud Consequences

## **Criminal Prosecution:**

- 18 USC 641 Criminal Embezzlement and Theft of Public Money
  - Knowingly converting funds or items to your use without the authority to do so.
  - Government must prove it was an intentional act.
  - Federal grant money is still the property of the US government even after it has been deposited in a grantee's bank account.
  - Criminal Penalties – Prison, Fines, Restitution
- 18 USC 1001 False Statements
  - Grant application signature and certifications, and in the quarterly financial statements made when drawing down funds.

## **Civil Prosecution:**

- 31 USC 3729 False Claims
  - Knowingly present, or cause to be presented, a false or fraudulent claim or payment or approval.
  - Actual knowledge, reckless disregard or deliberate ignorance.
  - Government does not need to prove fraudulent intent, preponderance of evidence.
  - Triple damages plus penalties between \$5,500 to \$11,000 per offense.

## **Administrative Action:**

- Civil Monetary Penalties
- Exclusion
- Suspension
- Debarment

# HHS-OIG Case Examples

FOR IMMEDIATE RELEASE

Monday, March 29, 2021

## **Davis Man Pays \$635,000 in Civil Settlement to Resolve Allegations of False Statements to Obtain Grant Frauds**

SACRAMENTO, Calif. — Owen Hughes, the sole proprietor of Eon Research Corporation in Davis, agreed to pay the United States \$635,000 to resolve allegations that he knowingly submitted false statements to the National Institute of Environmental Health Sciences to secure Small Business Innovation Research grant funds, Acting U.S. Attorney Phillip A. Talbert announced.

## **William Rosellini and His Companies Agreed to Pay \$50,000 and Be Excluded for 5 Years for Allegedly Violating the Civil Monetary Penalties Law by Inappropriately Drawing Down Funds from NIH Small Business Innovation Research Grants**

On October 13, 2020, William Rosellini, Nexeon Medsystems, Inc., Pulsus Medical, LLC, , and Nexeon Medsystems Puerto Rico Operating Company, Inc (collectively, "Nexeon"), entered into a settlement agreement with OIG in which they agreed to pay \$50,000 and be excluded from participation in all Federal health care programs for five years under 42 U.S.C. 1320a-7a and 42 U.S.C. 1320a-7(b)(7). The settlement agreement resolves allegations that Nexeon drew down funds from the HHS Payment Management System from National Institutes of Health (NIH) Small Business Innovation Research (SBIR) awards that were: (1) sent to an overseas affiliate without NIH approval, in violation of



# Report Suspected Fraud, Waste or Abuse to HHS OIG



HHS OIG Hotline  
<http://www.oig.hhs.gov>  
1-800-HHS-TIPS  
(1-800-447-8477)

- A Hotline complaint is an *allegation*.
- Hotline complaints are treated with privacy and discretion.
- OI conducts independent investigations and hotline complaints can provide helpful information.



# *Questions & Answers*

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## **Jonelle Soeffing**

HHS, OIG, Operations Officer

HHS OIG Hotline - <http://www.oig.hhs.gov>

